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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/524,858 | 02/18/2005 | Sadanobu Shirai | 2005_0152A | 3564 |
| 513 | 7590 | 10/01/2008 | EXAMINER | |
| WENDEROTH, LIND & PONACK, L.L.P. | | | AHMED, HASAN SYED | |
| 2033 K STREET N. W. | | | ART UNIT | PAPER NUMBER |
| SUITE 800 | | | 1618 | |
| WASHINGTON, DC 20006-1021 | | | MAIL DATE | DELIVERY MODE |
| | | | 10/01/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/524,858 | Applicant(s) SHIRAI ET AL. |
| | Examiner HASAN S. AHMED | Art Unit 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 June 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

- Receipt is acknowledged of applicants' RCE and petition for extension of time, both filed on 25 June 2008.
- The remarks filed on 23 May 2008 have been considered but are moot in view of the new grounds of rejection.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 23 May 2008 has been entered.

* * * * *

Response to Amendment

The declaration under 37 CFR 1.132 filed on 23 May 2008 is moot in view of the new grounds of rejection. However, it should be noted that the table on page 2 of the declaration indicates that none of the excipients were controlled for. Significant differences exist in the concentration of the styrene-isoprene-styrene block copolymer and petroleum resin. Furthermore, the new example contained polybutene, liquid paraffin, and dibutylhydroxytolune while the comparative example did not contain these ingredients. Conversely, the comparative example contained isopropyl myristate and

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polyisobutylene, which were not added to the new example composition. As such, examiner respectfully submits that the resulting rate of permeation may not be completely attributed to the difference in turobuterol concentration between the two samples, as the other excipients may have affected the rate of permeation as well. Without controlling for the other excipients, it is not possible to determine which variable resulted in the difference in rate of permeation.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 7,056,528 ("Bracht") in view of U.S. Patent No. 5,866,157 ("Higo").

Bracht teaches a transdermal therapeutic system comprising:

- 2.5-20% tulobuterol (see col. 3, line10);
- 2-20% of a C₁₁₋₂₂ fatty acid (see col. 4, lines 8-9);
- a rubber (styrene) (see col. 3, line 24);
- adhesive resin (tackifiers) (see col. 4, line 21); and
- plasticizer (see col. 4, line 21).

Bracht explains that the disclosed invention is beneficial in that it results in skin permeation of tulobuterol at rates sufficient to ensure therapeutic application (see col. 2, lines 32-34).

Bracht differs from the instant application in that it does not disclose concentrations of rubber, adhesive resin, or plasticizer.

Higo teach a percutaneous patch formulation (see col. 2, lines 32-39; Example 5). The disclosed patch is comprised of:

- an adhesive layer on a backing (see col. 6, line 7);
- said adhesive layer comprising:
 - 1-4% (w/w) tulobuterol (see col. 3, lines 39 and 58);
 - 0.01-20% (w/w) C₁₁-C₂₂ fatty acids (see col. 4, line 60 – col. 5, line 32);
 - 15-60% (w/w) rubber (see col. 3, line 64 – col. 4, line 9);
 - 10-70% (w/w) adhesive resin (see col. 4, lines 19 - 37); and
 - 10-60% (w/w) plasticizer (see col. 4, lines 38 - 59).

While Bracht and Higo do not explicitly teach all the instantly claimed percentages, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

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concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined tulobuterol, a rubber, an adhesive resin, a higher fatty acid, and a plasticizer into a patch formulation, as taught by Bracht in view of Higo. Motivation, as explained by Bracht, comes from the resulting skin permeation of tulobuterol at rates sufficient to ensure therapeutic application.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618